

SOVALDI® Tablets

(400 mg Sofosbuvir)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about SOVALDI tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your SOVALDI medicine. You may need to read it again.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT IS SOVALDI?

SOVALDI contains the active ingredient sofosbuvir which is given with other medicines to treat hepatitis C virus infection (also called HCV infection) in adults of 18 years and older.

SOVALDI works together with other medicines by lowering the amount of hepatitis C virus in your body and may lead to a cure of your HCV infection over at least 12 weeks.

Cure means the HCV virus is cleared from your blood (remains at an undetectable level) when measured 3 months after finishing all treatment. SOVALDI does not protect against re-infection with the HCV virus if cure has been achieved.

SOVALDI is for adults. SOVALDI has not been studied in children under the age of 18.

SOVALDI must always be taken together with other medicines as it will not work on its own.

BEFORE YOU TAKE SOVALDI

Who should not take SOVALDI

Together with your doctor, you need to decide whether SOVALDI is right for you.

Do not take SOVALDI if you are allergic to sofosbuvir or any of the other ingredients of SOVALDI. The ingredients of SOVALDI are listed in the product description section of this leaflet.

If you are pregnant think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

What should I tell my doctor before taking SOVALDI?

Tell your doctor if you:

- Taking any of the following medicines:
 - Rifampin
 - St John's Wort
- Are taking any anti-epileptic medicines.
- Are allergic to foods, dyes, preservatives or any other medicines.

- Are pregnant or planning to become pregnant. SOVALDI is commonly used together with ribavirin or with peginterferon alfa and ribavirin. Ribavirin can damage your unborn baby. It is therefore absolutely essential that you (and your partner) take all precautions not to get pregnant during this therapy. You and your partner must use an effective birth control method during ribavirin treatment and during the 6 months after ribavirin treatment. It is very important that you read the "Pregnancy" section in the ribavirin product information very carefully.
- Are breastfeeding or plan to breastfeed. It is not known if SOVALDI can pass into your breast milk and if it can harm your baby. Talk with your doctor about the best way to feed your baby.
- Have liver problems, other than hepatitis C.
- Have hepatitis B.
- Have HIV infection.
- Have any other medical condition.
- Have severe kidney problems or if you are on haemodialysis as the effects of SOVALDI on patients with severe kidney problems have not been fully tested.

WHAT IMPORTANT INFORMATION SHOULD I KNOW ABOUT TAKING OTHER MEDICINES WITH SOVALDI?

It is very important to let your doctor or pharmacist know what medications, herbal supplements, or vitamins you are taking.

Know the medicines you take. Keep a list of medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with SOVALDI. Do not start any new medicines while you are taking SOVALDI without first talking with your doctor or pharmacist.

HOW TO TAKE SOVALDI

Take the exact amount of SOVALDI your doctor has prescribed for you. Never change the dose on your own. Do not stop this medicine unless your doctor tells you to stop. The dose is one SOVALDI tablet orally, once daily.

If you forget to take SOVALDI

Do not miss a dose of SOVALDI. If you forget to take SOVALDI, take your missed dose right away unless it is almost time for your next dose.

Do not take a double dose to make up for a forgotten dose. Continue with your regular dosing schedule.

Do not stop taking SOVALDI unless your doctor tells you to. It is very important that you complete the full course of treatment to give the medicines the best chance to cure your hepatitis C virus infection.

Do not change your dose or stop taking SOVALDI without first talking to your doctor, unless you suspect a serious allergic reaction (see Allergy below).

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre: 13 11 26 (Australia) and 0800 764 766 (New Zealand) or go to the Accident and Emergency department at your nearest hospital if you think you or anyone else may have taken too many SOVALDI tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

Things you must not do

- Do not breastfeed. See "What should I tell my doctor before taking SOVALDI".
- Do not take SOVALDI after the expiry or "use by" date (EXP) printed on the bottle. If you take it after the expiry date has passed, it may not work as well.
- Do not take SOVALDI if the packaging is torn or shows signs of tampering.

Things to be careful of

Be careful driving or operating machinery until you know how SOVALDI affects you.

POSSIBLE SIDE EFFECTS

Like all medicines, SOVALDI can have side effects, although not everybody gets them.

If you take SOVALDI with ribavirin or peginterferon alfa and ribavirin, you may get one or more of the side effects below:

- feeling tired and irritable
- headache
- diarrhoea, feeling sick (nausea), being sick (vomiting)
- trouble sleeping (insomnia)
- rash, itchy skin
- loss of appetite
- feeling dizzy
- muscle aches and pains, pain in the joints
- fever, chills, flu-like symptoms
- shortness of breath, cough

Check with your doctor as soon as possible if you have any problems while taking SOVALDI, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, DO NOT TAKE ANY MORE SOVALDI and tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. Hypersensitivity reactions are very rare.

Ask your doctor or pharmacist if you don't understand anything in this list.

This is not a complete list of side effects possible with SOVALDI.

HOW DO I STORE SOVALDI?

Keep SOVALDI tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep SOVALDI tablets in a cool, dry place where it stays below 30°C.

Do not store SOVALDI or any other medicine in a bathroom or near a sink.

Do not leave SOVALDI in the car or on a window sill - heat and dampness can destroy some medicines.

Keep your SOVALDI tablets in the bottle with the cap tightly closed until you take them. If you take SOVALDI tablets out of their pack they may not keep well.

GENERAL ADVICE ABOUT PRESCRIPTION MEDICINES:

Talk to your doctor or pharmacist if you have any questions about this medicine or your condition.

Medicines are sometimes prescribed for conditions that are not mentioned in this leaflet. Do not use SOVALDI for a condition for which it was not prescribed. Do not give SOVALDI to other people, even if they have the same symptoms that you have. It may harm them.

This leaflet summarises the most important information about SOVALDI. If you would like more information, ask your doctor or pharmacist. Your doctor or pharmacist can give you information about this medicine that was written for doctors or pharmacists (Product Information/Datasheet).

PRODUCT DESCRIPTION

What SOVALDI tablets look like?

SOVALDI tablets are capsuled-shaped and yellow in colour. Each tablet has "GSI" on one side and "7977" on the other side of the tablet.

SOVALDI tablets are supplied in bottles containing 28 tablets.

SOVALDI tablet ingredients

Active Ingredients: sofosbuvir.

Inactive Ingredients:

- mannitol,
- microcrystalline cellulose,
- croscarmellose sodium,
- silicon dioxide and
- magnesium stearate.

Film-coating:

- polyvinyl alcohol,
- titanium dioxide,
- macrogol,
- talc purified,
- and iron oxide yellow.

AUST R 211019

SPONSOR

Australia:

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